DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 18, 2015

Health & Life Co., Ltd.
Ms. Sarah Su, Manager, Regulatory Affairs Department
9F, No. 186, Jian Yi Road
Zhonghe District, New Taipei City
Taiwan 23553
ROC

Re: K150311
Trade/Device Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL858GB
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: July 15, 2015
Received: July 17, 2015

Dear Ms. Su:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K150311

Device Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL858GB

Indications for Use:

HL858GB uses the oscillometric method to automatically measure systolic and diastolic blood pressure as well as heart rate. The measurement position is at human being's arm. All values can be read out in one LCD panel. The device is designed and recommended for use by people over the age of 18 with arm circumference ranging from approx.9 inches to 17 inches (23 cm to 43 cm) and for home use.

When the device detects the appearance of irregular heartbeats during measurement, an indicated symbol will appear with measuring readings. And the Near Field Communication (NFC) function allows user to transmit measuring result from the blood pressure monitor into NFC-enabled device simply and safely.

Besides, BP Category Indicator feature will judge blood pressure results into six levels based on WHO (World Health Organization) classification with corresponding bar segment on the edge of screen.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __V___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Devices Evaluation (ODE)

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PREMARKET NOTIFICATION

510(k) SUMMARY

(As Required By 21 CFR 807.92)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____ Date: FEB 06 2015

1. Submitter:

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2. Name of the Device:

Trade Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL858GB
Common Name: Blood Pressure Monitor
Classification Name: Non-invasive Blood Pressure Measurement System
Classification: Class II, 21CFR 870.1130
Classification Panel: 74 Cardiovascular
Product Code: DXN

3. Information for the 510(k) Cleared Device (Predicate Device):

Full Automatic (NIBP) Blood Pressure Monitor, Model HL858GA, K130563

4. Device Description:

HL858GB uses the oscillometric method to automatically measure systolic and diastolic blood pressure as well as heart rate. The measurement position is at human being's arm. All values can be read out in one LCD panel. The device is designed and recommended for use by people over the age of 18 with arm circumference ranging from approx.9 inches to 17 inches (23 cm to 43 cm) and for home use.

The device will display a symbol  or  , to indicate the detection of irregular heartbeat rhythm as defined as a rhythm is more than or less than 25% from the average heartbeat intervals during the measurement. Additionally, after measurement, the BP Category Indicator function will show the information with the readings on the screen for the user tracking their blood pressure level. Furthermore, the Near Field Communication (NFC) function allows user to transmit measuring results from the blood pressure monitor into NFC-enabled device simply and safely.

5. Intended Use

HL858GB uses the oscillometric method to automatically measure systolic and diastolic blood pressure as well as heart rate. The measurement position is at human being's arm. All values can be read out in one LCD panel. The device is designed and recommended for use by people over the age of 18 with arm circumference ranging from approx.9 inches to 17 inches (23 cm to 43 cm) and for home use.

When the device detects the appearance of irregular heartbeats during measurement, an indicated symbol will appear with measuring readings. And the Near Field Communication (NFC) function allows user to transmit measuring result from the blood pressure monitor into NFC-enabled device simply and safely.

Besides, BP Category Indicator feature will judge blood pressure results into six levels based on WHO (World Health Organization) classification with corresponding bar segment on the edge of screen.

6. Comparison of device to predicate device:

Product Specification Comparison Table of Subject device HL858GB and predicate device HL858GA (K130563)

Item	Predicate device HL858GA (K130563)	Subject device HL858GB
Method of measurement	Oscillometric	Same as left
Range of Measurement	Rated Range of cuff pressure 0 ~ 300 mmHg Rated Range of Determination 40 ~ 280 mmHg Pulse 40 ~ 199 beats/minute	Same as left
Accuracy	Pressure ＋/－ 3mmHg Pulse ＋/－ 5%	Same as left
Inflation	Automatic inflation (Air pump)	Same as left
Deflation	Automatic air release control valve	Same as left

Exhaust	Automatic exhaust valve	Same as left
Display	Liquid Crystal Digital Display	Same as left
Power Supply	AA/LR6 (1.5V) Alkaline Battery × 4	Same as left
Storage/ Transportation Environment	- 25℃ ~ + 70℃ (- 13℉~ +158℉), ≦ 93% R.H.	Same as left
Operating Environment	5℃ ~ 40℃ (41℉~104℉), 15% ~ 93% R.H. 700 ~ 1060 hPa	Same as left
Material	ABS housing and ABS keys	Same as left
Sets of memory	3×40,total 120	1×99,total 99
Number of Push Button	4	Same as left
Storage pouch	Yes	Same as left
Cuff size	Arm circumference 9~17 inches (approx.23~43cm)	Same as left
Unit Weight	8.73 ± 0.35 oz (247.5 ± 10 g) (Cuff and Batteries Excluded)	Same as left
BP Category Indicator	Yes	Same as left
Irregular Heartbeat Detector	Yes	Same as left
Data Link function	Yes (Via Usb cable)	Yes (Via NFC)

Changes from the predicate device HL858GA (K130563):

*Changing the sets of memory.

*Modifying the data-link feature from USB cable into Near Field Communication (NFC).

These modifications have been verified and validated to demonstrate that it does not affect the safety and effectiveness of subject device HL858GB.

7. Discussion of Clinical Tests Performed:

HL858GB is compliant to the standard of ISO 81060-2: Second Edition 2013-05-01 Non-invasive sphygmomanometers- Part 2: Clinical validation of automated measurement type. The results of this clinical investigation show that the required limits for mean difference and standard deviation are fulfilled by the subject device HL858GB in the group of 85 subjects with qualified distribution. Thus, all the relevant activities were performed by designate individual(s) and the results demonstrated that the predetermined acceptance criteria were fully met.

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The subject device was tested to evaluate its safety and effectiveness, including the followings:

a. **EMC Test**: IEC 60601-1-2 Edition 3:2007-03, Medical Electrical Equipment - Part 1-2: General requirements for safety - collateral standard: Electromagnetic compatibility - Requirements and Tests

b. **Radio Frequency Wireless Test:**

-ETSI EN 301 489-1, Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements

-ETSI EN 301 489-3, Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 40 GHz

-ETSI EN 302 291-1, Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Close Range Inductive Data Communication equipment operating at 13,56 MHz; Part 1: Technical characteristics and test methods

-ETSI EN 302 291-2, Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Close Range Inductive Data Communication equipment operating at 13,56 MHz; Part 2: Harmonized EN under article 3.2 of the R&TTE Directive

c. **Safety Test**:

-IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

-IEC 60601-1-11:2010, Medical electrical equipment-Part 1-11:General Requirement for basic safety and essential performance– Collateral Standard: Requirements for medical electrical systems used in the home healthcare environment

-IEC 80601-2-30 Edition1.1 2013-7 Medical electrical equipment-Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.

d. **FCC Test:** FCC 47 CFR Part 15, Subpart B

e. **Biocompatibility Test:**

-ISO 10993-1:2009, Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process

-ISO 10993-5:2009, Biological evaluation of medical devices-Part 5: Tests for In Vitro cytotoxicity

-ISO 10993-10:2010, Third Edition Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization

f. **Reliability Test**: IEC 80601-2-30 Edition1.1 2013-7 Medical electrical equipment-Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.

g. **Risk Assessment**: ISO 14971:2007 Second Edition, Medical devices - Application of risk management to medical devices

h. **Software Verification and Validation**:

-IEC 62304 Ed.1.0 (2006), Medical device software - Software life cycle processes,

-IEC 60601-1-4 Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems, edition 1.1

i. **Usability Validation**: IEC 62366:2007 Medical devices - Application of usability engineering to medical devices

9. Conclusions:

The subject device was tested and fulfilled the requirements of those standards mentioned above, and it's concluded that the subject device is substantially equivalent to the predicate device.